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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,305	02/24/2004	R. Elaine Fulton	NEL-0018/NP	1520

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/784,305	Applicant(s) FULTON ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 7-9 is/are ~~allowed~~ allowable. *see 4/3/06*.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/24/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed January 23, 2005 is acknowledged and entered. Claims 1-4 and 7-15 are pending. Claims 4 and 7-10 are under examination. Claims 1-3 and 11-15 remain withdrawn from consideration, being drawn to non-elected subject matter. The restriction requirement is deemed proper and made FINAL.

Claim Objections

2. Claims 4 and 7-10 are objected to for a minor informality. The sequence identifiers must be notated correctly, "SEQ ID NO: 1", for example. Correction is required.

Specification

3. The amendment filed January 23, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

--Further, examples of the strains of A116 and mA116 scFv antibodies are listed below. They were deposited on November 26, 2003 at the International Depositary Authority of Canada, Bureau of Microbiology, Health Canada, at 1015 Arlington Street, Winnipeg, Manitoba, Canada, R3E 3R2. The deposit information are as follows:

<u>Strain</u>	<u>Accession Number</u>
A116-6	191103-01
mA116-4	191103-02

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mA116-6	191103-03
mA116-14	191103-04
mA116-15	191103-05
mA116-16	191103-06--

Applicant notes that the insertion of the examples of mA116 scFv Ab into the specification does not constitute new matter since the disclosure of such antibodies are found in the reference, Alvi *et al.*, *Viral Immunology*, 2003, 16:213-222. Applicant points to page 2, lines 15-17 of the specification for support of the cited reference. Applicant also points to page 18, lines 1 and 2 of the specification for support that the reference was incorporated by reference. The Office does not find support in the specification for the legal incorporation of the information described above.

MPEP 2163.07(b) [R-3] Incorporation by Reference

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See >37 CFR 1.57 and < MPEP §608.01(p) for Office policy regarding incorporation by reference.

37 CFR 1.57 (b) (c). Incorporation by reference.

(b) Except as provided in paragraph (a) of this section, an incorporation by reference must be set forth in the specification and must:

- (1) Express a clear intent to incorporate by reference by using the root words "incorporat(e)" and "reference" (e.g., "incorporate by reference"); and
- (2) Clearly identify the referenced patent, application, or publication.

(c) "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material" is material that is necessary to:

- (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;

- (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or

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(3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

With regard to 37 CFR 1.57 (b)(1) and (2), Applicant has not expressed a clear intent to incorporate the Alvi *et al.* reference. Applicant's specification recites, "In addition, the List of Prior Art Literatures referred to in the Background of the Invention section is incorporated by reference herein." This statement incorporates a list of references, not the Alvi *et al.* reference itself.

With regard to 37 CFR 1.57 (c), Applicant is attempting incorporate essential material by reference from a source other than a U.S. patent or U.S. patent application publication. The incorporation by reference of Alvi *et al.* is improper because Alvi *et al.* is not a U.S. patent or U.S. patent application publication. The antibody scFvs listed above are essential material because they are required to provide a written description of the claimed invention.

In view of the deficiencies of the specification, Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The claim recites, “The SBP tagged recombinant scFv Ab fusion protein of claim 4, wherein said scFv Ab is a mA116 scFv Ab.” Previously the claim recited, “The SBP tagged recombinant scFv Ab fusion protein of claim 4, wherein said scFv Ab is mA116 scFv Ab.” Applicant is attempting to claim a genus of mA116 scFv antibodies for which Applicant does not have support.

The specification and the previous version of claim 10 led the Office to the conclusion that there is one scFv mA116 antibody, which is why Applicant was required to provide deposit information for the one antibody. Now Applicant is informing the Office that there are many mA116 antibody scFvs, not just one. Applicant looks to Alvi *et al.* for support of A116-6, mA116-4, mA116-6, mA116-14, mA116-15, and mA116-16. The incorporation by reference of Alvi *et al.* appears to be improper (see above). Even if the incorporation by reference were proper, the specification itself does not support the idea that mA116 is a genus of antibodies, rather, a single antibody. Presenting mA116 as a genus of antibodies is not support by the specification.

Note that the Office has found support in Alvi *et al.* for all of the scFvs except mA116-6. Lacking evidence to the contrary, Applicant does not have support for mA116-6.

5. The following rejections are withdrawn in view of Applicant’s amendment:
 - The rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement with respect to the biological material mA116, is withdrawn in view of Applicant’s amendment to the

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claim. Note that if the new matter from claim 10 is removed, this rejection may be reinstated.

- The rejection of claims 5 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of Applicant's amendment, removing the terms in question.
- The rejection of claims 4, 7 and 9 under 35 U.S.C. 102(b) as being anticipated by Aubrey *et al.* (*Biol. Chem.* 2001, 382:1621-1628, "Aubrey"), is withdrawn in view of Applicant's amendment. The claims now require that the fusion protein comprise the amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 1, or the amino acid sequence of SEQ ID NO: 2. Aubrey, nor the prior art teach or suggest SEQ ID NO: 1 or SEQ ID NO: 2.
- The rejection of claims 4 and 7-10 under 35 U.S.C. 103(a) as being unpatentable over Alvi *et al.* (*Hybridoma and Hybridomics*, 2002, 21(3):169-178, "Alvi") in view of Keefe *et al.* (*Protein Expression and Purification*, 2001, 23:440-446, "Keefe") and Aubrey, is withdrawn in view of Applicant's amendment. The claims now require that the fusion protein comprise the amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 1, or the amino acid sequence of SEQ ID NO: 2. None of Alvi, Keefe and Aubrey, nor the prior art teach or suggest SEQ ID NO: 1 or SEQ ID NO: 2.

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Conclusion

7. Claims 4 and 7-9 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen 4/3/06

Stacy B. Chen
Primary Examiner
April 3, 2006